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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,211	11/16/2001	Peter M. Bonutti	BON-2950-2	7013

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EXAMINER	
THALER, MICHAEL H	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,211	BONUTTI ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-62,64-73,75,77-88,90 and 91* is/are pending in the application.

4a) Of the above claim(s) *82* is/are withdrawn from consideration.

5)☒ Claim(s) *57-62,64,65,72,73,75,77-79,90 and 91* is/are allowed.

6)☒ Claim(s) *66,70,71,80,81 and 83-88* is/are rejected.

7)☒ Claim(s) *67-69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 66, 70, 80, 83-85, 87 and 88 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kratoska et al. (6,183,443). Kratoska et al., in figures 7A-7C, show tubular sheath 200 and an array of filaments 207 (as described in col. 24, lines 57-61) which extend along an inner side of the passage of sheath 200. The Kratoska et al. sheath 200, passage and array of filaments 207 are resiliently expandable from a contracted condition to an expanded condition, wherein said sheath is biased inwardly to the contracted condition (col. 24, lines 23-43 and col. 24, line 62 to col. 25, line 7). The array of filaments 207 blocks contact between an object inserted in the passage and the sheath (col. 24, lines 57-61). Filaments 207 are "filaments" since they are thin and elongated. Alternatively, it would have been obvious that ribs 207 are "filaments" since they are thin and elongated. As to claim 70, the Kratoska et al. sheath is inherently engageable by a member having an oval cross-section and is inherently expandable by inserting this member therein. The member having an oval cross-section is not part of the claimed combination. As to claims 80 and 88, the longitudinal stiffening wire in each rib described in col. 25, lines 56-63 is considered to be either part of the claimed filament (along with the rib) or the entire claimed filament. Each wire is made of a

flexible, non-stretchable material which is different than the material of the sheath. As to claim 85, the Kratoska et al. array of filaments, along with the sheath, is connected to proximal end portion 208.

Claims 81 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratoska et al. (6,183,443). As to claim 81, Kratoska et al. fail to disclose that each filament (the longitudinal stiffening wire in each rib described in col. 25, lines 56-63) has a circular cross-section. However, it was well known in this art that wires, by definition, typically have a circular cross-section. It would have been obvious that each of the Kratoska et al. wires has a circular cross-section for this reason. As to claim 86, Kratoska et al. fail to disclose the claimed inner and outer rings. However, it was well known in this art to connect hubs to tubular members by inner and outer clamping rings to positively secure the hubs to tubular members. It would have been obvious to so secure the Kratoska et al. hub 208 to tubular member 206 along with its filaments for this reason. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 66, 70, 71 and 83-85 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.

103(a) as obvious over Wilk (5,312,417). Wilk shows an expandable cannula comprising tubular sheath 18 having a passage which extends between opposite end portions of the sheath and an array of filaments 20, the sheath, passage and array of filaments being resiliently expandable from a contracted condition to an expanded condition, wherein the sheath is biased inwardly to the contracted position (since it is made of elastic material as indicated in col. 3, lines 40-48). The array of filaments 20 inherently blocks contact between an object inserted in the passage and the sheath since the filaments are disposed along an inner side of sheath 18 as indicated in col. 3, lines 55-56. For example, an object such as an instrument having a circular cross-section having an outer diameter which is only slightly larger than the inner diameter of the array of filaments 20 would inherently be blocked from contacting the sheath since filaments 20 would be located between the instrument and the sheath. Alternatively, it would have been obvious that the array of filaments 20 blocks contact between an object inserted in the passage and the sheath since the filaments are disposed along an inner side of sheath 18 and thus are located between the object and the sheath. As to claim 70, the Wilk sheath is inherently engageable by a member having an oval cross-section and is inherently expandable by inserting

this member therein. The member having an oval cross-section is not part of the claimed combination. As to claim 71, Wilk shows pump means (the source of the insufflation pressure which is attached to port 14) which inherently expands the sheath to some extent due to the high pressure. Alternatively, Wilk shows pump means (the source of the hydraulic or pneumatic pressure in the embodiment described from col. 4, lines 64 to col. 5, line 4).

Claims 57-62, 64, 65, 72, 73, 75, 77-79, 90 and 91 are allowed.

Claims 67-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed March 1, 2004 have been fully considered but they are not persuasive. The array of filaments 207 of Kratoska et al. blocks contact between an object inserted in the passage and the sheath (col. 24, lines 57-61). Although Kratoska et al. refers to friction caused between the outer surface of a guide catheter and the inner surface of the sheath 200 (col. 25, lines 65-67), it is clear that the inner surface referred to is on portion 207 of sheath 200 and the circular inner surface of shaft 206 in the embodiment of only one rib 207 shown in figure 7C. However, in the embodiment having several

ribs (which is not shown in the drawings), it is clear that a device 214 having a circular cross section would inherently be spaced completely from the circular inner surface of shaft 206 by the several ribs 207 since the ribs would be located at spaced intervals completely around the device 214 between the device 214 and the circular inner surface of shaft 206. Further, Kratoska et al. refers to additional spacing between the outer wall of the intravascular device and the inner wall of sheath shaft 206 in col. 24, lines 57-61. As to Wilk, although Wilk refers to an organ or organ part (which may have a shape other than perfectly circular) being drawn into the sheath, an object such as an instrument having a circular cross-section having an outer diameter which is only slightly larger than the inner diameter of the array of filaments 20 could be drawn into the sheath and would inherently be blocked from contacting the sheath since filaments 20 would be located between the instrument and the sheath.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
4/7/04

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731